

Dieter's Tea Regulations

California Code of Regulations, Title 17

10200. Dietary Supplement.

(a) "Dietary supplement"

(1) Means an article (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

(A) A vitamin,

(B) A mineral,

(C) An herb or other botanical,

(D) An amino acid,

(E) A dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or

(F) A concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

(2) Means a product that

(A) Is labeled as a dietary supplement and

(B) Is intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form, or if not intended for ingestion in such a form

(C) Is not represented for use as a conventional food, or as a sole item of a meal or the diet; and

(3) Does

(A) Include an article that is approved as a new drug in compliance with Health and Safety Code section 111550, subdivision (a) or (b), certified as an antibiotic under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. section 357, and/or licensed as a biologic under the Public Health and Safety Act, 42 U.S.C., section 262 and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food, unless the article, when used as or in a dietary supplement under the conditions of use set forth in the labeling for such dietary supplement is adulterated under California Health and Safety Code section 110545, and

(B) Not include

1. An article that is approved as a new drug in compliance with Health and Safety Code section 111550, subdivision (a) or (b), certified as an antibiotic under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. section 357, and/or licensed as a biologic under the Public Health and Safety Act, 42 U.S.C., section 262, or

2. An article authorized for investigation as a new drug, antibiotic, or biologic for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, and which was not, before its approval, certification, licensing, or authorization, marketed as a dietary supplement.

(b) A dietary supplement may be a food or a drug, or both a food and a drug, as these terms are defined in Health and Safety code sections 109935 and 109925.

NOTE: Authority cited: Sections 100275, 110065, and 110100, Health and Safety Code.

Reference: Sections 110175, 110290, 110545, 110620, 110625, 110630, 110660, 110705, 110760, 110765 and 110770, Health and Safety Code.

(1) Amend Section 10750 to read:

10750. Label Requirements for Foods and Dietary Supplements.

(a) Any food or dietary supplement, as defined in Title 17, California Code of Regulations, Division 1, section 10200, that contains any amount of a substance listed in Table 10750 A shall comply with the following:

(1) The label of foods and dietary supplements that have a total surface area available to bear labeling of 12 square inches or more shall bear the following notice in the manner prescribed in paragraph (a) (2) of this section:

NOTICE: This product contains (name of substance(s) and common name(s) if different). Read and follow directions carefully. **Do not use if you have or develop diarrhea, loose stools, or abdominal pain because (insert common name) may worsen these conditions and be harmful to your health.** Consult your physician if you have frequent diarrhea or if you are pregnant, nursing, taking medication, or have a medical condition.

(2) The notice required by paragraph (a) (1) of this section shall:

(A) Be enclosed by a 0.5 point box rule with 2.5 points of space around the notice,

(B) Utilize at least one point leading,

(C) Have a type that is kerned so the letters do not touch,

(D) Be all black or one color type, printed on a white or other neutral contrasting background,

(E) Utilize single easy to read type style as Helvetica Regular and upper and lower case letters,

(F) Be in type size no smaller than 8 point,

(G) The word "NOTICE" shall be in all upper case letters, and

(H) The sentence "Do not use if you have or develop diarrhea, loose stools, or abdominal pain because (insert common name) may worsen these conditions and be harmful to your health." shall be underlined and highlighted by bold or extra bold type, such as Helvetica Black.

(3) Foods and dietary supplements in small packages that have a total surface area available to bear labeling of less than 12 square inches shall include the notice required by paragraph (a) (1) in the format specified in (a) (2) in a package insert or a tag attached to the package and bear the following label notice in the manner prescribed in paragraph (a) (4) of this section:

NOTICE: **Do not use if you have or develop diarrhea, loose stools, or abdominal pain because (insert common name) may worsen these conditions and be harmful to your health.** See package insert (or attached tag) for additional information.

(4) The notice required by paragraph (a) (3) of this section shall:

(A) Be enclosed by a 0.5 point box rule with 2.5 points of space around the notice,

(B) Utilize at least one point leading,

(C) Have a type that is kerned so the letters do not touch,

(D) Be all black or one color type, printed on a white or other neutral contrasting background,

(E) Utilize single easy to read type style such as Helvetica Regular and upper and lower case letters,

(F) Be in type size no smaller than 6 point,

(G) The word "NOTICE" shall be in all upper case letters, and

(H) The sentence "Do not use if you have or develop diarrhea, loose stools, or abdominal pain because (insert common name) may worsen these

conditions and be harmful to your health." shall be underlined and highlighted by bold or extra bold type, such as Helvetica Black.

(b) This section does not apply to foods and dietary supplements containing the leaf gel or leaf juice of aloe (*Aloe ferox* Mill. or *Aloe vera* (L.) N.L.Burm.) or concentrations thereof, providing that the food or dietary supplement does not contain another substance listed in Table 10750 A.

Table 10750 A - Listed Substances

Common Name	Plant Part	Botanical Name
aloe also known as cape aloe	latex	<i>Aloe ferox</i> Mill.
aloe also known as aloe vera	latex	<i>Aloe vera</i> (L.) N.L.Burm., also known as <i>Aloe</i> <i>barbadensis</i> Mill. or <i>Aloe</i> <i>vulgaris</i> Lamk.
buckthorn	berry	<i>Rhamnus catharticus</i> L.
cascara also known as cascara sagrada	bark	<i>Rhamnus purshianus</i> DC. also known as <i>Rhamnus</i> <i>purshiana</i> DC. or <i>Frangula</i> <i>purshiana</i> (DC.) JG Cooper
frangula also known as buckthorn	bark	<i>Rhamnus frangula</i> L. also known as <i>Frangula alnus</i> Mill.
rhubarb root also known as chinese rhubarb	root	<i>Rheum officinale</i> Baill., <i>Rheum palmatum</i> L., <i>Rheum</i> <i>rhaponticum</i> L., or <i>Rheum</i> <i>tanguticum</i> , Maxim. ex Balf.
senna also known as Alexandria senna or Tinnevely senna	leaf or pod	<i>Senna alexandrina</i> P. Mill. also known as <i>Cassia senna</i> L., <i>Cassia angustifolia</i> Vahl, <i>Cassia acutifolia</i> Del., or <i>Senna</i> <i>angustifolia</i> (Vahl) Batka

senna also known as sicklepod senna	leaf or pod	<i>Senna obtusifolia</i> (L.) Irwin and Barneby also known as <i>Cassia</i> <i>obtusifolia</i> (L.)
senna	leaf or pod	<i>Senna tora</i> (L.) Roxb. also known as <i>Cassia tora</i> (L.)

NOTE: Authority cited: Sections 100275, 110065, and 110100, Health and Safety Code.
Reference: Sections 110175, 110290, 110660, 110705, 110760, 110765 and 110770, Health and Safety Code.